

US Spine 510(k)

JUN - 6 2008

4. 510(k) Summary according to 807.92(c)

Contact: Trace Cawley
US Spinal Technologies
3600 FAU Blvd., Suite 101
Boca Raton, FL 33431
561-367-7463

Trade Name: Preference Pedicle Screw System

Classification: 21 CFR §888.3070 Pedicle screw spinal system
§888.3050 Spinal interlaminar fixation orthosis

Class: II

Product Codes: KWQ, KWP, MNH, MNI

Indications for Use:

The Preference Pedicle Fixation System is intended to help provide immobilization and stabilization of spinal segments as an adjunct to fusion of the lumbar and/or sacral spine, specifically as follows:

When used as a pedicle screw fixation system of the non-cervical posterior spine in skeletally mature patients, the Preference Pedicle Fixation system is indicated for one or more of the following: (1) degenerative spondylolisthesis with objective evidence of neurologic impairment, (2) fracture, (3) dislocation, (4) spinal tumor, and/or (5) failed previous fusion (pseudarthrosis).

In addition, when used as a pedicle screw fixation system, the Preference Pedicle Fixation System is indicated for skeletally mature patients: (a) having severe spondylolisthesis (Grades 3 and 4) of the fifth lumbar-first sacral (L5-S1) vertebral joint; (b) who are receiving fusions using autogenous bone graft only; (c) who are having the device fixed or attached to the lumbar and sacral spine (L3 and below); and (d) who are having the device removed after the development of a solid fusion mass.

When used as a posterior, non-cervical, non-pedicle screw fixation system, the Preference Pedicle Fixation System is intended for the following indications: (1) degenerative disc disease (as defined by back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies), (2) spinal stenosis, (3) spondylolisthesis, (4) fracture, (5) pseudarthrosis, (6) tumor resection and/or (7) failed previous fusion.

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Device Description:

The Preference Pedicle Screw System is comprised of a variety of monoaxial and polyaxial pedicle screws sizes, hooks, connectors and rods. All implantable components are manufactured from medical grade titanium alloy (Ti6Al4V-El) or Cobalt Chrome.

Predicate Device(s):

The Preference Pedicle Screw System was shown to be substantially equivalent to previously cleared devices and has the same indications for use, design, function, and materials used. These devices include the LTD Fixation System from US Spine (K041625 and K062785) and the Quantum Spinal System from Pioneer Surgical (K080518).

Performance Testing:

The pre-clinical testing performed indicated that the Preference Pedicle Screw System is substantially equivalent to predicate devices.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN - 6 2008

US Spinal Technologies
% Mr. Tracc Cawley
3600 FAU Boulevard
Suite 101
Boca Raton, FL 33431

Re: K081296
Trade/Device Name: Preference Pedicle Screw System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: Class II
Product Code: MNH, MNI, KWP, KWQ
Dated: May 6, 2008
Received: May 7, 2008

Dear Mr. Cawley:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Mark N. Melkerson", with a stylized flourish at the end.

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number: K081296

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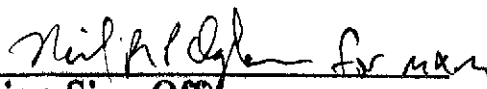
Prescription Use ☒
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use ☐
(21 CFR 807 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)


(Division Sign-Off)

Division of General, Restorative,
and Neurological Devices

510(k) Number K081296